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PATENT MAINTENANCE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
FOGH, et al.
Serial No.: 09/601,138
Filed: October 26, 2000
For: METHOD FOR TREATING
ACUTE INTERMITTENT...

) Art Unit: 1652
)
)
) Examiner:
)
) US PATENT & TRADEMARK
) Washington, D.C. OFFICE
)
) May 9, 2001
)
) Docket No.: FOGH=1

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ELECTION WITH TRAVERSE

Commissioner of Patents
Washington, D.C. 20231

S i r :

1. In response to the restriction mailed March 9, 2001, Applicants elect group I (direct enzyme therapy), with traverse.

All claims relate to treatment of a disease caused by deficiency of an enzyme belonging to the heme biosynthetic pathway. The distinction here is between (I) therapy by supplying an enzyme directly, and (II) therapy by supplying the enzyme indirectly by providing expressible DNA encoding that enzyme.

The Examiner concedes that PCT unity rules apply. Under PCT rule 13.1, the claims, to have unity, must relate "to one invention only or to a group of inventions so linked to form a single general inventive concept".

The general inventive concept is that of restoring the deficient enzyme function. Both (I) and (II) accomplish this, and in a related manner as the supplied enzyme is the same.

PCT rule 13.2 says that for a group of inventions, unity is fulfilled "where there is a technical relationship among those inventions involving one or more of the same or corresponding technical feature". The "corresponding features" are directly or indirectly supplying an enzyme belonging to the heme biosynthetic pathway to a deficient subject.

Annex B, Part 2 to the PCT Administrative Instructions presents examples concerning unity of invention. Example 17 reads:

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Claim 1: Protein X.

Claim 2: DNA sequence encoding protein X. AM 4:17

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

If there is unity between a protein per se and the DNA encoding it, there likewise should be unity between a therapeutic method-of-use of a protein, and a therapeutic method-of-use of the DNA encoding it to express that very protein in vivo.

2. In response to the species restriction, applicants elect species 1, with traverse. This traversal is on the grounds that generic claims are allowable, see MPEP 809.02. At least claims 1, 5-20, 22-32, and 35 are generic.

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Respectfully submitted,

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